# TAB 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

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|---|---|---|
| THE CITY OF HUNTINGTON, | : | Civil Action |
| Plaintiff, | : | No. 3:17-cv-01362 |
| v. | : | |
| AMERISOURCEBERGEN DRUG CORPORATION, et al., | : | |
| Defendants. | : | |
| CABELL COUNTY COMMISSION, | : | Civil Action |
| Plaintiff, | : | No. 3:17-cv-01665 |
| v. | : | |
| AMERISOURCEBERGEN DRUG CORPORATION, et al., | : | |
| Defendants. | : | |

BENCH TRIAL - VOLUME 35
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JULY 7, 2021

opioid prescribing?

**A.** Yes. It was looking at people prescribing improperly for no medical reason and fraud.

MS. MAINIGI: Your Honor, at this time, I would like to tender Dr. Deer as an expert in pain management and the standard of care for pain management.

THE COURT: Any objection?

Hearing none, the Court finds Dr. Deer to be an expert in pain management and the standard of care for pain management.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Dr. Deer, in your experience, who is it that makes the decision to write a prescription for an opioid medication to a patient?

**A.** It would be the physician or clinical practice person, which may be a nurse practitioner in some instances.

**Q.** And, in your opinion, is it appropriate to prescribe opioids for pain management in various instances?

**A.** In the correct patient, it can be very appropriate.

**Q.** Now, let's turn to the basis for your expert opinion. At a high level, what is the question you were asked to look at and answer in this case?

**A.** So, I was asked to look at the standard of care in West Virginia from my arrival here in 1994 until 2021 and how it

changed regarding opioid prescribing and really what happened in West Virginia.

**Q.** And were you -- you were focused specifically on West Virginia across the board?

**A.** That's correct.

**Q.** Okay. And are you also familiar with what was happening nationally at the same time?

**A.** As I testified earlier, I'm very involved in national societies, so I do know the national, really, overview. And, also, I know a lot of the folks nationally who were giving lectures on proper opioid prescribing back in those days who we may talk about later.

**Q.** So, how did you go about answering the question that you were charged with?

**A.** Well, so --

**Q.** What did you do?

**A.** First of all, you know, I've been here a long time. I don't feel as old as I am, but that's how life goes. So, I've been here a long time. And so, I have my personal experience, you know, treating well over a hundred thousand patients over the years.

But, also, you know, I have looked at what happened with, you know, policies around the state legislature, what happened with societies, which we have members of societies in West Virginia, what happened with the education of

doctors. So, I looked at all of those factors and I think it really gives a good insight, in my opinion, of what happened here and what's going on today.

**Q.** And were you able to form an opinion, Dr. Deer, with reasonable degree of certainty about how the standard of care for the use of opioid medications and the treatment of pain changed between the early 90s through today?

**A.** I felt very confident that I have a very good impression of how it changed from 1994 until 2021.

MS. MAINIGI: Matt, if we could put up the next slide, please.

BY MS. MAINIGI:

**Q.** Dr. Deer, did you help us prepare this demonstrative which provides an overview of where you're going with your opinions?

**A.** I did.

**Q.** So, tell us at a high level, what is your opinion?

**A.** Well, so, at a high level, there's -- in my career there's been three main phases in West Virginia. There was the initial when I first got here and right before I got here there was a liberalization of prescribing of opioids for basically anyone who complained of pain around the state. And then, that went on until around 2010.

**Q.** And it started about when?

**A.** Probably in the late 80s as legislation and articles

started to appear in national and international literature that it was a human right to be treated for pain. So, probably late 80s. And then, in the early 90s, we saw more prescribing. And then, around 1996, it changed dramatically.

**Q.** And why did it change dramatically in '96?

**A.** Because new drugs came along that were really said to be less addictive and, certainly, most physicians believed that to be true.

**Q.** And are you referring specifically to Oxy, which is manufactured by Purdue?

**A.** The primary drug was OxyContin. I mean, MS Contin and thera-gesic patches were also in that group, but OxyContin was the primary drug that was going to be the wonder drug, if you will. We all believed that to be probably the case based on the marketing and research at the company who developed that drug.

**Q.** Now, so, in this first phase, which you said went until about 2010; is that right?

**A.** I can -- again, that's a number I can live with. Certainly, some of those lines are blurry of what exact years that may be.

**Q.** So, did you see then the standard of care evolve towards prescribing more opioids?

**A.** Oh, absolutely. You know, as a referral-only practice,

you know, we would get -- you know, if you get a patient sent to you from Oceana on ten pills a day and you take over their care, you know, that's 300 pills a month. That's 360 pills a year for one patient. You can't just take them off that day, right? You have to make adjustments and you have to try other things. So, we would get those patients, you know, and, certainly, we would have to find solutions for them because, obviously, that's -- I never felt that was going to be an appropriate long-term dose for the patients. So, we saw that from -- really, as the 90s progressed, we saw more and more of that, all the way -- and we'd get people off, 80-85 percent of people either off or reduced by half. But then, new patients would come in. So, the funnel kept filling up. So, I saw it firsthand every day of my practice.

**Q.** So, let me pause on one thing. You mentioned -- we spoke just a moment ago about Purdue. Did you personally have any professional interactions with Purdue during this time period, this first phase?

**A.** I did. So, Purdue Frederick was a company that presented research that OxyContin was less addictive and long-term solution for chronic people who needed opioids. They also sponsored several county societies. So, for CAMC, for Thomas, for St. Francis.

I would go out to Roane County, for example, or Raleigh

County, or Huntington to give ground rounds and they would have a sponsor for the event. And so, they would both give the honorary to the speaker, which was $500 or a $1,000.00. They would also sponsor the event itself. And so, I did work in that capacity and --

**Q.** Did there come a time when you decided to stop doing work for Purdue?

**A.** Well, so, you know, I -- from 1996, when they came out until probably the early part of 2000, I really felt that the teaching around the country that long-term opioids were better than short-term was correct until I started seeing more and more of what was going on with the drug OxyContin.

And when I gave a lecture -- just to be clear, when I gave a lecture they were sponsoring a program on, I always talk about the same thing. I talk about procedures as a way to spare people from opioids when possible. So, I would talk about that and I wouldn't use their slides. And so, that was an issue with them a bit.

**Q.** Did something happen in the early '00s that caused you to stop even participating in anything they sponsored?

**A.** It did. Two things happened. I actually heard some of their speakers talk about you could give people with alcohol addiction their drug and it wouldn't be a problem. I felt that was totally crazy. Every -- every bit of information says that's wrong.

And then, Dr. Haddox, who was their Medical Director, talked a lot about, you know, that no one was really addicted, they were undertreated, you give them more and more. And I heard him -- we were speaking together at Embassy Suites at a meeting put on by the State Medical Association. I was speaking on procedures, he was speaking on opioids, and I really felt that was bad information to give physicians. So, we had a real break in our thought processes.

**Q.** Now, after you had this experience with Purdue, did you stop prescribing opioids?

**A.** No. I think opioids -- again, it's a complicated issue. When we get referrals on a patient that's been on an opioid for three years and they say it's helping them and their urine screen is good and they've been compliant with their family doctor, you can't easily just take them off their opioid. You have to find a solution to help them.

Most people that get to see us want to get off of opioids. That's why they often request from the family physician, I want to go see Dr. Kim or Dr. Deer, one of my colleagues. And so, we then come up with a strategy, a plan.

Many of those people, for example, have never been to physical therapy. Something that simple. We have a physical therapy department. Many of those people had a,

you know, a joint problem that we can easily burn the joint and help them, but they've never been offered that. So, a lot of times, it was just the family physician didn't know what options existed. And so -- so, we didn't quit prescribing opioids in general and, in fact, we didn't quit prescribing Oxycodone in patients who were on it already, but we did try to find other solutions and I no longer believed the comment that it wasn't addictive because I started seeing some people have an addiction in the community.

**Q.** Now, let's shift over to your second phase. So, you've got the first phase. And describe to me what you saw happening in this 2010 to 2015 time period with the second phase.

**A.** Well, so, you know, we started seeing more discussion about the problem, you know, and I think it became -- people started pushing back a bit. We had -- and we'll talk in more detail, but we had everyone saying you have to up the dose. You have to treat the patient with opioids. You have to look at the fifth vital sign and make sure they are treated properly.

And then, in 2010 or so, we starting seeing people like myself pushing back and saying I'm not sure that's right. We need to look at it carefully.

And, in 2012, the West Virginia Legislature asked for

advice from myself and others and they created the West Virginia act that made pain clinics be certified. And what I mean by that is, if someone gave more than 51 percent of their patients a controlled substance, they fell under that legislation even if they were a family doctor because, at that time, you could be a family physician calling yourself a pain clinic giving people opioids all day long, right? That was appropriate under the rules before 2012 in West Virginia.

In 2012, that legislation said you have to meet certain criteria to be treating pain chronically. And I think that was a big step forward in '12. It wasn't enough probably to change the standard of care, we'll talk more about that later, but it helped.

**Q.** Let's talk about the third phase then, 2015 through -- through the present. Describe for us what was happening particularly in West Virginia during that phase.

**A.** So, in '15 to '21, I think, again, we've seen a really good change in West Virginia, I think, and it goes back to several factors. One is the CDC came out with guidelines and while it's a national thing, local physicians in West Virginia -- and, again, they were -- they were written originally for primary care and family practice.

People who had given people high dose opioids for years read the CDC guidelines. 15 morphine equivalents should be

what the goal is, or less. 98 at the most unless someone is end of life. And that really made people change their prescribing some, not all, but it helped.

Then the SEMP guidelines came out in '16 and we published those. That helped because then they had a way to enforce or adjudicate the CDC guidelines in their practice.

And then, thirdly, and I think probably most importantly for me because if you watch my prescribing taking people over in this '10, '11, which was up here because I got those people coming to me that way versus '18 and now through '21.

We saw the 2018 legislation in West Virginia about limiting prescribing, which was the best thing that's happened to our state, in my opinion, as far as this issue goes, really limit how much family physicians gave patients before they sent them to see me.

So, now, most patients sent to see us, unless they're cancer patients on minimal or no opioid. So, that conservatism phase, I think, has been very -- in my opinion, very good for the people in West Virginia.

**Q.** So, in addition to your own practice, did you see a change in this later third time period in prescribing trends in West Virginia?

**A.** Oh, absolutely. I think if you look at the West Virginia data from the last few years overall, hydrocodone

and oxycodone both are way down as prescribed for patients. Also, many family physicians from all over the state, really, that '18 law scared them a bit because they had been prescribing in ways that were not anywhere remotely familiar to the '18 law. So, I had phone calls from probably, you know, a third of the family physicians in West Virginia asking me what they should do. And so, that was good because, in the past, I didn't get those phone calls. So, I think that was a good thing.

**Q.** And so, it sounds like you've also changed or adjusted your own opioid prescribing in the last several years?

**A.** Oh. Absolutely. So, you know, to give you an example, in 2005, when we received a patient on high dose OxyContin and, again, they had no signs of addiction, their drug -- we screen everybody with a drug screen from the day we meet them. The drug screen was good. The Board of Pharmacy was good, but they were on this high dose. We would have to figure out how to get them off that drug and do other things, right, make -- sometimes, it took a long time because the patient had really bad problems. Sometimes, it took a long time because of insurance approval of procedures.

For example, Medicaid would not approve procedures, but they would approve the drug. So, it really -- we take Medicaid or practices that do take Medicaid. So, we saw all

that going on and sometimes it would take us three or four years to get someone down below the 15 morphine equivalence or off the medication.

And then, 2020, if I'd get 100 patients in a month, maybe two or three will be on opioids.

So, I mean, I can't tell you the difference. It's amazing. You can see it in my numbers, for example, because, again, remember, we take only referred patients. So, we only see you if your doctor has already treated you for at least three to six months.

So, I think it's been striking to me what those three things we just talked about, the CDC, SEMP and the state legislation did to improve that.

**Q.** So, let's come back for a moment and define standard of care. Can you tell the Court what you mean when you use that phrase?

**A.** So, standard of care means what a reasonable doctor would do within their field of medicine in a situation and that's the standard of care.

**Q.** And are standards of care typically written down or formalized?

**A.** Some are written down. For example, guidelines that we write for devices, if it says give antibiotics before surgery, if we don't do that and the person gets an infection, you're going to probably be in trouble. So,

that's a written standard of care.

Some aren't written; they're understood. For example, you know, I just read a book on the Spanish Flu and Johns Hopkins in those days, they would bleed you for Spanish Flu and that was standard of care. Didn't work very well in 1918. But today, if you did that, you would lose your license. So, I mean, standard of changes based on, you know, common knowledge. Everyone decided that was a bad idea. So, that's not written down, but it doesn't need to be.

**Q.** So, the standard of care is not static? It can be dynamic?

**A.** It's usually dynamic in most things. There are certain rules that I think that always stay the same, but in many areas of care, it changes based on new evidence or research and that's why research is so important.

**Q.** And are prescribers expected to prescribe medications consistent with whatever the then existing standard of care is?

**A.** I don't know about the word expected, but I think physicians do follow the standard of care. So, if you're told you're undertreating people and, again, back in that first phase, I was often called to M&M conferences at hospitals to give my opinion was the doctor undertreating someone because a complaint would come in.

So, if you're told that you're undertreating people, you get more likely to treat people with opioids. If you're told you're overtreating people, you tend to back off. So, I think they do change with -- I think doctors do change their prescribing habits based on the standard of care.

**Q.** And to your -- it sounds like this is what you're alluding to. To your experience, can there be consequences for prescribers if they don't follow the existing standard of care?

**A.** Sometimes. I mean, there are people that I see patients from who I think did a terrible job with the standard of care, but nothing happened to them because the patient had no harm. But other people may lose their license.

And you asked me about the federal prosecutors I've worked with in the past and people have lost licenses and gone to jail for prescribing without a medical reason or they can lose their Board of Medicine license or they can get sued in civil court for malpractice.

**Q.** So, Dr. Deer, who has access to the information needed to determine whether a prescriber is prescribing consistent with the standard of care?

**A.** Well, I would -- I will give you my best answer and it may be not totally correct. I think the Board of Pharmacy, the DEA and, eventually, the Board of Medicine if it's given

to them.

**Q.** And in your experience, Dr. Deer, do wholesale distributors have access to information that would allow them to determine whether a particular doctor is prescribing within the standard of care?

**A.** Not in my --

MR. FITZSIMMONS: Objection.

THE WITNESS: I'm sorry, sir.

MR. FITZSIMMONS: I need to object. I believe it's outside the scope of the qualification for the standard of care. We're now bringing in acts of the distributorship which, according to the report, is limited not to -- does not include the distributorship conduct whatsoever.

THE COURT: Well, overruled. I'm going to let him answer, if he knows, from his own personal knowledge.

THE WITNESS: I don't have any knowledge of any distributor involvement in that based on my personal experience.

BY MS. MAINIGI:

**Q.** So, I want to focus back on the standard of care for pain management.

THE COURT: I think I should sustain the objection in view of his last answer, Ms. Mainigi. You go ahead.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** When did you see the standard of care begin to change?

**A.** That's a complicated question. Could you rephrase that? I'm not sure I understand.

**Q.** Yeah. No, that is -- that is not a good question.

So, for example, when you were in medical school, was it the standard for physicians to routinely prescribe opioid medications for chronic pain?

**A.** So, when I was at WVU, you know, we didn't have any lectures on pain at all and that was pretty common. Now, I'm working with some people at Hopkins to make a good curriculum for medical schools. And the only thing I saw with opioids there was a doctor named Dr. Moss (phonetic), who was Head of Palliative Care. And that was really all I saw opioid-wise when I was a medical student. I would see people after surgery get opioids, usually Tylox or Percocet. And so, that was about it in med school.

**Q.** And so, did you come by the mid-90s to know of a concept called pain as the fifth vital sign?

**A.** So, when I was leaving UVA coming here, I was starting to see at UVA people on a lot of pills a day, short-acting pills. And so, I was starting to see a change a little bit in the early '90s, but it wasn't to the point it got to much later.

So, when I came to West Virginia, I started hearing about the fifth vital sign as I went to society meetings and

Joint Commission and things of that nature. So, that became a term that was really propagated around the United States.

You know, you have your blood pressure. You have a pulse. You have your respiratory rate. You have your temperature. That's what most -- you know, I have a daughter who is a nurse. That's what most nurses would check in the hospital.

And then, it was added to the Veterans Administration, which I know there's one down in Huntington, as well as the Joint Commission accredited hospitals, a fifth vital sign, which was pain assessment and treatment.

**Q.** And so, pain as the fifth vital sign, that meant that that was something like blood pressure that actually got asked about at the hospital or tested?

**A.** Once that became accepted as an important factor, it was required. You know, when you asked me earlier about CAMC, one of the reasons I became Medical Director of CAMC of Pain, they had to meet the Joint Commission requirements as pain for the fifth vital sign. It meant that every patient that walks in the hospital, inpatient or outpatient, or to the VA, had to ask the pain level and follow that throughout the care and then make adjustments to the pain and get the pain below a five out of ten.

**Q.** And so, were there several organizations that promoted pain as the fifth vital sign?

**A.** There were several. I think the biggest was American Pain Society, which was a society dealing with mostly non-interventional pain.

**Q.** And have you ever been a member of the American Pain Society?

**A.** I was. I joined that society, like many other societies, early on, never played any leadership role there in any fashion because they were more non-interventional, but they had a journal called Pain, which was the highest rated journal in our field for many years, and we published an article on stimulation of the spine there in 2015 that's a landmark article.

**Q.** And, at the time, did you view the American Pain Society as a respected organization?

**A.** They had some of the more experienced doctors in the field, mostly non-interventional, but some of the more well-published doctors. So, yes, they were well respected back in those days.

MS. MAINIGI: Your Honor, I'd like to put up on the screen DEF-WV-02395.

Matt, if you could put that up, please.

BY MS. MAINIGI:

**Q.** Do you recognize, Dr. Deer, this document from the American Pain Society?

**A.** I do. It was widely seen around our field.

**Q.** Okay. And can you describe it? What is it?
**A.** So, this is a document by the society, American Pain Society, from 1995, right after I got to West Virginia and the year after. And then, it's a statement from the -- presidential address from Dr. James Campbell, who I know well from Johns Hopkins. He was from the Department of Neurosurgery there and he was giving the keynote address and he called for this change and then their board agreed with him and made a push to make that important.
**Q.** So, James Campbell was the Head of the American Pain Society at the time?
**A.** Yes, he was.
**Q.** And he was -- he practiced at Johns Hopkins?
**A.** He still does. I had a call with him about an experiment in the spinal fluid a few months ago, but he still -- but he doesn't see patients any longer. He does research only now, I think.
**Q.** So, if you could --

MS. MAINIGI: Matt, if we could highlight the statement from Dr. Campbell at the top.

BY MS. MAINIGI:

**Q.** If you could read that out loud, please?
**A.** I'll try my best. That's a long way from me.
**Q.** And I'm sorry, Dr. Deer. You have a binder in front of you.

**A.** Oh, okay. I think I can do it.

**Q.** Okay.

**A.** It's not on, but I'll try my best to read that from here. I feel like I'm at the Department of Motor Vehicles.

**Q.** You're at the opthamologist.

**A.** Vital signs are taken seriously. If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly. We need to train doctors and nurses to treat pain as a vital sign. Quality care means that pain is measured and treated. Dr. Campbell.

**Q.** You did a good job with that. Thank you.

**A.** Thanks. I can't go any smaller than that from this distance, please.

**Q.** Now, is it not up on your screen, Dr. Deer?

**A.** No. There's nothing up on my screen.

**Q.** Oh, okay.

**A.** It's dark.

**Q.** The binder in front of you -- well, next time, we'll turn to the binder.

**A.** Oh, thank you.

**Q.** So, this document was in '95 and then OxyContin came out in 1996; is that right?

**A.** Not exactly. OxyContin, I believe, was actually approved in '95. I think '96 was when Purdue Frederick

started to market OxyContin as a product, but I think it was approved in '95, if I remember correctly.

**Q.** Now, in your opinion, did these messages from Dr. Campbell and the American Pain Society affect the medical community?

**A.** Oh, they were -- they were hugely impactful [sic] and people made changes immediately to their practice because of this fifth vital sign.

**Q.** How do you know that?

**A.** I lived through it. Everybody admitted to the hospital had to be treated -- to go home like, for example, if you had your knee replaced, at that time, Dave Santrock was doing a lot of knee replacements at my hospital, one of my dear friends. And so, he would replace your knee and before you'd go home Day 2 or 3, but after this came about, you couldn't go home unless your pain was down to a 4.

So, most doctors, I mean, there are people like me. I can go do a nerve block. I can do a femoral nerve block to help your knee pain and you might go home.

But most doctors don't do that type of procedure. So, they would give you, you know, pills because they had to get you below 4. So, when people left the hospital, they had a month's pills and they went back to their family doctor. And then, many times, they stayed on their pills because they've got chronic knee pain even though they had the

replacement. So, that really changed greatly anybody that went to the hospital for any reason, including outpatient treatment, how they were treating them.

MS. MAINIGI: Your Honor, I would like to move to admit 02395 into evidence.

THE COURT: Any objection?

MR. FITZSIMMONS: No objection.

THE COURT: It's admitted.

By MS. MAINIGI:

**Q.** I'm going to ask you -- and let's let you turn in your binder, Dr. Deer --

**A.** I have the screen now.

**Q.** -- if that's helpful. Oh, you have the screen now? Okay.

MS. MAINIGI: Matt, if you could put on the screen DEF-WV-03074, it should be the next document in the binder.

BY MS. MAINIGI:

**Q.** Now, this is a document from the VA entitled Pain as the Fifth Vital Sign Tool Kit. Are you familiar with this document?

**A.** Yes, I am.

**Q.** And what's the date on the document, just so we can place it?

**A.** October 2000.

**Q.** Now, let's turn to Page 13, if you could, of the

document, and there's a section there, Section 4, called The Pain Screening Process. Could you read that section, please?

**A.** Be happy to. Pain as the fifth vital sign is a strategy for promoting increased attention to unrecognized and undertreated pain among patients receiving care in the Veterans Hospital Administration healthcare system. The strategy calls for a routine screening, where patients are asked whether they are experiencing pain and are then asked to rate the intensity of their pain using the 0 to 10 numeric rating scale on which 0 equals no pain while 10 represents the worst possible pain. The number reported by each patient is the pain score and should be documented in the medical record. The presence of pain at any level serves as a cue to the provider to conduct additional assessment and to initiate interventions designed to promote pain relief, as clinically indicated.

**Q.** So, is this document from the VA an example of an organization promoting the under -- promoting the fact that pain is undertreated and should be dealt with?

**A.** That's correct.

MS. MAINIGI: Your Honor, at this time, I would like to move for the admission of 03074 into evidence.

THE COURT: Any objection?

MR. FITZSIMMONS: No objection, Your Honor.

THE COURT: It's admitted.

By MS. MAINIGI:

**Q.** Now, that was the VA. Are you aware if during this time period, Dr. Deer, hospitals also began to adopt policies to address the undertreatment of pain?

**A.** So, most hospitals that anyone in this room will go to, hopefully, are accredited because that's important that they meet standards. Joint Commission adopted the fifth vital sign as one of those standards of approval of your hospital facility or outpatient surgery center.

**Q.** And let me ask you to turn -- well, you can look at the screen, if you'd prefer, but it is -- the document is WV-2693 in the binder. Should be the next tab. It's the Joint Commission pain standards which have already been admitted for a limited purpose under Dr. Gilligan. Are these, in fact, the Joint Commission pain standards?

**A.** Those are that document, yes, ma'am.

**Q.** And those are from 2001?

**A.** Correct.

**Q.** And do you have an opinion, Dr. Deer, as to what impact this guidance, along with the APS guidance and the VA guidance, had on the standard of care for prescribing opioids during this time period?

**A.** I feel it greatly shifted, in my experience, the standard of care towards more opioid prescribing for anyone

admitted to any hospital.

**Q.** Now, this guidance doesn't expressly tell doctors to prescribe more opioids, does it?

**A.** It does not.

**Q.** So, why did it change the standard of care?

**A.** Because, you know, there's an old saying if you have a hammer that looks like a nail in medicine where you do the same thing for everyone. So, if you went to see in a hospital that had someone who could do a shoulder block after shoulder surgery, you may get that. It may help your shoulder pain to get you home. We do a lot of those today in 2021.

But if you didn't have someone to do a block if you had a shoulder replacement or a rotator cuff repair, that's quite painful. So, to get you out of the hospital, you know, originally, it said pain below 5, but as you saw in that thing I just read, it said any pain at all. If you complain of pain, many physicians who are good physicians, who didn't -- wasn't trying to cause harm, gave the person opioids in the hospital by IV and then shifted to pills to let them go home because, otherwise, they couldn't meet the standard -- the Joint Commission standards.

**Q.** And this change in the standard of care during this time period, was that consistent with the practice you saw at hospitals in West Virginia?

**A.** Oh, absolutely.

**Q.** And, to your knowledge, did this pain as the fifth vital sign concept affect prescribing by doctors outside of the VA and outside of hospitals, as well?

**A.** I think it did because, again, when those patients went back to their home, then they often had been taking opioids successfully, giving them pain relief. The family doctor would often keep them on that medication.

**Q.** Now, were prescribers at the time who prescribed more opioids in accordance with that changing standard of care, were they, in your opinion, acting reasonably in light of the information available to them at the time?

**A.** Based on their knowledge base and their options, they were, based on the information.

**Q.** Now, are you aware of whether wholesale distributors had any involvement in any of these documents?

MR. FITZSIMMONS: Judge, I'm going to object. I thought we already established that it's (unintelligible) --

COURT REPORTER: I'm sorry, sir. I'm having trouble hearing you. Is your mic on?

MR. FITZSIMMONS: I'm sorry. Is my mic on?

COURT REPORTER: I don't think so.

MR. FITZSIMMONS: It's not. I'm sorry. I apologize.

I thought we already objected once as to the area of a

distributorship's action and this is -- I believe Your Honor sustained that objection and this question is specific, trying to elicit now distributorship conduct by this witness, who has already testified he knows nothing about that.

THE COURT: Well, I'm going to let him answer the question if he can. The reason I sustained the last objection was that he said he didn't -- he didn't know.

MR. FITZSIMMONS: That's correct, Judge. That's why I'm objecting again.

THE COURT: That's --

MR. FITZSIMMONS: And unless he changes his testimony --

THE COURT: I'll reserve my ruling and let you question him a little further, Ms. Mainigi.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Do you remember the question, Dr. Deer?

**A.** Please repeat it.

**Q.** Absolutely. Do you have -- are you aware of any distributor involvement in any of these documents that we've been talking about, the Joint Commission, the VA tool kit?

**A.** I have no knowledge of any distributor roles or actions.

THE COURT: I'll overrule the objection, Mr.

Fitzsimmons.

BY MS. MAINIGI:

**Q.** Now, at the same time --

THE COURT: The question went to what he personally knew and he said he didn't have any knowledge and I think the answer was appropriately admitted.

MR. FITZSIMMONS: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Dr. Deer, around the same time that the Joint Commission issued its standards in 2001, did the DEA issue a statement related to the treatment of pain?

**A.** They did.

**Q.** Okay.

MS. MAINIGI: I'm going to ask, Matt, that we put on the screen MCWV-01522, which is already admitted for limited purpose under Dr. Gilligan.

BY MS. MAINIGI:

**Q.** And, Dr. Deer, is this a statement that you were referring to?

**A.** It is.

**Q.** And this statement from the DEA, as well as 21 health organizations in 2001, is this statement consistent with the standard of care that you just testified about?

**A.** That is one of the components physicians looked at for their decision making.

**Q.** Now, Dr. Deer, I think you helped us prepare another slide that identified some of the key developments in West Virginia and nationally related to the changing standard of care from the 1990s through the present; do you recall that?

**A.** I do recall that, yes.

**Q.** Okay.

MS. MAINIGI: Your Honor, I'm going to put a demonstrative on the screen and let me explain to you what it is.

Matt, if you could put -- put it up there.

What this is, Your Honor, is Dr. McCann -- this was an admitted exhibit under Dr. McCann. It was, I think, a 1006 summary charge that Your Honor admitted. For the record, it's P-44711_0009 and what it shows, according to Dr. McCann, is the distribution of oxycodone and hydrocodone by all distributors from 1997 to 2019.

BY MS. MAINIGI:

**Q.** Does this chart look familiar to you, Dr. Deer?

**A.** Yes, it does.

**Q.** Okay. So, we just talked about a few major events that occurred. You just testified about the launch of OxyContin and introduction of pain as the fifth vital sign in 1996; is that correct?

**A.** That's correct.

MS. MAINIGI: So, Matt, let's add that to our

chart.

BY MS. MAINIGI:

**Q.** And then, you also testified about the VA's adoption of pain as the fifth vital sign in 2000 and the Joint Commission's adoption in 2001; is that correct?

**A.** That's correct.

MS. MAINIGI: So, let's add those to the chart.

BY MS. MAINIGI:

**Q.** And then, you just testified right now about the DEA statement promoting pain relief?

**A.** That's correct.

MS. MAINIGI: And let's add that to the chart.

BY MS. MAINIGI:

**Q.** So, let's shift over to what was happening in West Virginia in this time period. Let's take a look at WV-01219, which is an admitted document. It was admitted during Dr. Waller's testimony. What -- what is this document, Dr. Deer?

**A.** This is a Board of Medicine statement clarifying the use of opioids for the treatment of chronic non-malignant pain.

**Q.** And I think if we turn to Page 2, we'll see the date on this document. What is that date?

**A.** July 14th, 1997.

MS. MAINIGI: And let's go back to the first page

and let's take a look at the second paragraph, Matt, if you could highlight that.

BY MS. MAINIGI:

**Q.** And if you could read that to us, Dr. Deer?

**A.** Happy to. The purpose of this statement is to clarify the Board of Medicine's position on the appropriate use of opioids for patients with chronic non-malignant pain so that these patients will receive quality pain management and so that their physicians will not fear legal consequences, including disciplinary action by the board, when they prescribe opioids in a manner described in this statement. It should be understood that the board recognizes that opioids are appropriate treatment for chronic non-malignant patient in selected patients.

**Q.** So, first, let's just define chronic non-malignant pain. What is that?

**A.** So, chronic pain is pain that lasts -- and it's been defined different ways, but pain that lasts more than 12 weeks. Some people define that as chronic pain. Others have described chronic pain as pain that lasts longer than you would expect tissue healing to occur.

So, for example, if you have a trauma to your leg, you would expect it to get better over time and it doesn't. And you still have nerve abnormalities. So, that's two definitions that are widely used.

**Q.** And non-malignant pain would mean non-cancer pain basically?

**A.** Correct. That means your pain is not cancer-related pain.

**Q.** So, before this time period, let's say before 1997, were doctors generally prescribing opioid medications for chronic non-malignant pain in their ordinary practice?

**A.** They were, but not -- not very often and not very high doses. They were using short-acting drugs like Percocet, Tylox, Dermabond. You know, and they were -- they were afraid to go to higher doses because of fear of the Board of Medicine taking their license if they gave too much medication in those early days.

**Q.** So, what do you take from this statement issued by the Board of Medicine in 1997? What's your interpretation of that?

**A.** Well, I think it goes back to what was going on in the country we've talked about a little bit. The fifth vital sign came out, as far as recommendation from APS. Doctors were starting to think that pain was a right. The World Health Organization had said that it was right for cancer pain. Then that was then transferred over to non-cancer pain. And I think the Board of Medicine in West Virginia, getting advice from doctors, we all thought that, you know, longer-acting drugs may be better and safer. And from

people like the Federation of State Medical Boards that they should be allowed treatment of pain because they thought it was undertreated and undertreatment became -- became a big fear then of doctors after this type of statement came out.

**Q.** Well, let's take a look at the fourth paragraph in this document on the first page.

MS. MAINIGI: Matt, if you could blow that up.

BY MS. MAINIGI:

**Q.** So, that paragraph reads a physician need not fear disciplinary action by the board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in the medical records. What do you take from that statement?

**A.** I take from this that, you know, this is one of the things we talked about earlier. When I would get someone to come in and see me after three years of pain treatment on a really high dose, I think doctors felt comfortable just going up on the dose rather than referring them to a specialist. So, this is, I think, very -- a very common practice of, you know, upping the dose until someone got better or got a side effect.

**Q.** So, at the bottom of the first page there is a suggested references section, and there are two articles that are listed as references. Are you familiar with those articles?

**A.** I'm very familiar with both those articles.

**Q.** And can you just summarize for me at a high level what your understanding is of the point of those articles?

**A.** So, the Portenoy article is famous, famous in our field, because Russell Portenoy, a neurologist in New York, he had treated cancer patients for many years. He said that you should keep upping your dose until you get the effect, which would be --

MR. FITZSIMMONS: Judge, I'm going to object. He's setting forth what the author of an article meant, which is hearsay, and I don't see any foundation for him to be doing that at this point. So, this is improper.

THE COURT: I will sustain that one, Ms. Mainigi.

MR. FITZSIMMONS: Thank you, Judge.

MS. MAINIGI: Your Honor, he -- well, I can establish some foundation.

THE COURT: All right. Go ahead.

BY MS. MAINIGI:

**Q.** Dr. Deer, are you familiar with the Russell Portenoy article?

**A.** I know the article well and the physician pretty well.

**Q.** And was it a seminal article in the treatment of pain during this time period?

**A.** It was.

**Q.** Was it widely read and distributed?

**A.** It was.

**Q.** And did the West Virginia Board of Medicine cite it as a suggested reference to physicians in West Virginia?

**A.** They did.

MS. MAINIGI: Your Honor, I think I've established foundation. And I think this would fall under 703. The question that I would come back to, with your permission to pose to Dr. Deer is, could he describe at a high level the gist of what Dr. Portenoy was saying in his article.

THE COURT: I don't think 703 makes it admissible. He can -- he can refer to it as the basis of his opinion. Can you get around it under one of the exceptions to the hearsay rule?

MS. MAINIGI: Your Honor, I think we really just need it for notice. We're not going for the truth of the matter. We just -- it was notice to the medical and healthcare community about what the standard of care was at the time.

THE COURT: Which exhibit are we talking about here? I've lost my place.

MS. MAINIGI: Oh, Your Honor, it's in your binder.

MR. FITZSIMMONS: 1219.

THE COURT: What's the number, the exhibit?

MS. MAINIGI: 1219, Your Honor, in the binder, and you'll see it's a --

THE COURT: Well, hasn't it already been admitted?

MS. MAINIGI: The document -- let me just double check. This document has been admitted. I'm just asking him about the suggested references that the Board of Medicine tells doctors in West Virginia to go look at. The other point of that -- the other hearsay --

THE COURT: Just a minute.

MS. MAINIGI: Yes, Your Honor.

THE COURT: Mr. Fitzsimmons?

MR. FITZSIMMONS: Judge, this is a footnote and she's now asking this witness to tell us what's in the article. It's hearsay at its greatest.

THE COURT: I will sustain the objection, Ms. Mainigi.

MR. FITZSIMMONS: Thank you, Your Honor.

MS. MAINIGI: Your Honor, if I might just --

THE COURT: He can -- he can refer to it as the basis of his opinion, but I don't think he can get into the substance of the -- of the article. I'll sustain the objection.

MS. MAINIGI: Okay. Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Was this article from Dr. Portenoy, Dr. Deer, an article that physicians during this time period could have reasonably relied upon?

**A.** Many did.

**Q.** And could you elaborate on that, please?

**A.** Many physicians adopted the philosophy that you upped the dose of opioids until someone got better, their pain below a 3 or a 4, or they had a side effect. And there was no ceiling, was what Dr. Portenoy always stated in his lectures and things around the country. And so, you should keep going up even to a thousand milligrams a day without any fear of any problems in a patient. That was his teaching and the article's gist.

**Q.** And how about the second article, is this an article you're also familiar with, The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement?

**A.** I am.

**Q.** And was that an article that was relied upon, to your knowledge, by doctors in West Virginia in their prescribing?

**A.** I believe that it was.

**Q.** And in what direction did that article take them, as far as prescribing?

**A.** Just for the Court's knowledge, these two societies, I was members of both. They were the two largest pain societies in the country at the time. They had a lot of, I would say, older non-interventional physicians writing these statements who were opioid experts and they both -- they recommended that patients be treated with opioids, again, to

proper doses without side effects.
**Q.** So, did this Position Statement from the Board of Medicine in West Virginia, did that get distributed to physicians in West Virginia?
**A.** It did. I think all physicians in West Virginia received that board policy.
**Q.** Okay. If I could ask you to turn to the next document, which is WV-03003, can you identify this document for us, please, Dr. Deer?
**A.** Yes. We now receive our Board of Medicine newsletters via e-mail, but this was -- they used to mail this to all the doctors licensed in West Virginia every quarter or this was one for a year, it looks like, from January to December, but it would come to all licensed physicians in West Virginia.
**Q.** So, this went to all licensed physicians?
**A.** I believe so, yes.
**Q.** Okay. And if you turn to Page 6 of the document, which is the very last page, at the top of that page, on the right, it says board issues statement on the use of opioids for the treatment of chronic non-malignant pain. To your knowledge, was that the statement we were just looking at?
**A.** Yes, it was.
**Q.** Okay. And could you go ahead and read this, the rest of this statement, please?

**A.** Certainly.

MR. FITZSIMMONS: Judge, I'm going to object to having him read the news information into the record at this point.

MS. MAINIGI: Your Honor, I can go ahead and move this document into evidence. So, why don't I go ahead and do that. And it would come under the ancient document exception, Your Honor. Documents like this, also, this newsletter, were actually admitted through Dr. Waller.

THE COURT: Any objection?

MR. FITZSIMMONS: I don't know what the date was, Judge, on that.

THE COURT: This is '97. December of '97. January --

MR. FITZSIMMONS: It doesn't make the date then, I don't believe.

MS. MAINIGI: It does. January '98 is the cutoff.

MR. FITZSIMMONS: If it's January of -- if it is, it is.

THE COURT: Well, let me look. Statement in a document that was prepared before January 1st, 1998 and whose authenticity is established. It's admitted.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** So, Dr. Deer, could you just read that statement from

the board, please?

**A.** The Board's ad hoc committee on Americans with disabilities had several meetings with interested parties on the issue of pain management. At the July, 1997 meeting, the full board approved the committee's Position Statement on the use of opioids for the treatment of chronic non-malignant pain. In September, 1997, the board mailed its Position Statement to all physicians currently holding an active medical license in the State of West Virginia. If you are interested in receiving a copy of this Position Statement, please contact the board.

**Q.** Thank you, Dr. Deer.

MS. MAINIGI: Matt, let's go back to our chart.

THE COURT: Just a minute. Just so the record will be clear, I admitted the exhibit, DEF-WV-03003, under the ancient documents records exception to the hearsay rule, which is found in 803(16).

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Dr. Deer, would you add the West Virginia Board of Medicine statement from 1997 to this chart?

**A.** Oh, absolutely. It changed people's perceptions.

MS. MAINIGI: Matt, if we could go ahead and add it, please. Oh, it's there. Sorry.

BY MS. MAINIGI:

**Q.** Dr. Deer --

MS. MAINIGI: Actually, Your Honor, would now be a good time for a break before I turn to another document?

THE COURT: Yes, I think it would be.

You can step down during the break, Dr. Deer.

THE WITNESS: Thank you, sir.

THE COURT: We'll be in recess for about ten minutes.

(Recess taken)

(Proceedings resumed at 10:38 a.m. as follows:)

MS. MAINIGI: Your Honor, I apologize. The witness will be right out of the men's room.

THE COURT: That's all right. We usually check to see if everybody is back, but this time we didn't do that.

(Pause)

Thank you, Dr. Deer.

BY MS. MAINIGI:

**Q.** All right, Dr. Deer, we left off in '97 in West Virginia. Do you recall from 1998 something called the Intractable Pain Act in West Virginia?

**A.** I recall it well.

MS. MAINIGI: I'm going to ask, Matt, if you could put up on the screen 03106. And that is also in the binder.

BY MS. MAINIGI:

**Q.** What was the Intractable Pain Act? Let's start

with that, Dr. Deer.

**A.** So it was an act that talked about prescribing medication for patients who had intractable pain.

**Q.** And what is intractable pain? What's that definition?

**A.** So intractable means that reasonable attempts have been made to treat someone's pain. For example, I have an overuse injury of my tendon in my ankle right now. And, so, if I got to physical therapy, it didn't help me. If I had injections, it didn't help me. If a medication didn't help me, that would be intractable pain. It doesn't go away with normal treatment.

**Q.** Is it similar to chronic pain?

**A.** Well, it can be chronic pain. So you can have chronic pain -- let's say, for example, you're a lawyer and you sit all day and your back hurts and it hurts you all the time, that's chronic pain. But it may not be intractable because you go home, you stretch, you get in the hot tub, you feel fine. Right? So it's chronic pain but not intractable.

Intractable means it's so severe that you just can't get rid of it and it affects your life, your, your psyche, and everything about you. It becomes part of you almost.

MS. MAINIGI: Your Honor, this document that is 03106, which is the Intractable Pain Act from the West Virginia legislature, I'd ask the Court to take judicial notice of this document.

THE COURT: Any objection?

MR. FITZSIMMONS: No objection, Your Honor.

THE COURT: It's judicially noticed and admitted.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** So taking a look at the, the document where it starts with at the top "An act," could you read that, please, Dr. Deer?

**A.** Yes. "An act to amend Chapter 30 of the Code of West Virginia, one thousand nine hundred thirty-one, as amended by adding thereto a new article, designated Article 3(a), relating to limiting disciplinary actions against certain health professionals prescribing, administering, or dispensing controlled substances in the management of intractable pain."

**Q.** So this -- the concept that's reflected in this act, Dr. Deer, was that consistent with the '97 Board of Medicine Physician Statement that we looked at earlier?

**A.** It was very consistent with what the Board of Medicine had said a year earlier.

**Q.** And what was the goal here, to your understanding?

**A.** I think the goal was really intended to be a good goal to, to treat people who needed treatment. So I think the intent was, was, was, you know, at the time reasonable and felt to be a need.

**Q.** And if we look at the bottom of the first page going on to the second page, starting with "a physician shall not --"

MS. MAINIGI: And, Matt, why don't we go ahead and highlight the relevant provisions there. The highlighted portion I think would be Number 2.

BY MS. MAINIGI:

**Q.** So Number 2 refers to disciplinary sanctions -- that a physician would not be subject to disciplinary sanctions by the state if the physician prescribed, administered, or dispensed pain-relieving controlled substances for the purpose of alleviating or controlling intractable pain when, in the case of intractable pain involving a patient who is not dying, the physician discharges his or her professional obligation to relieve the patient's intractable pain even though the dosage exceeds the average dosage of a pain-relieving controlled substance, if the physician can demonstrate by reference to an accepted guideline that his or her practice substantially complied with that accepted guideline.

What do you take that to mean?

**A.** Well, I think it was telling physicians that if someone had chronic pain that was non-cancerous, they still should be treated like a cancer patient basically with higher doses without fear of retribution against the doctor and if they

documented why they were doing it in their chart.

**Q.** And would you say that -- we just looked at that Board of Medicine statement from '97 which had references to the Portnoy article and others. Do you recall that?

**A.** I do.

**Q.** And would you say that an article like that was an accepted guideline or reference for physicians at the time?

**A.** It became an accepted standard.

**Q.** Now, if we take a look at the last sentence there, still under Number 2, it says evidence of non-compliance with an accepted guideline is not sufficient alone to support disciplinary or criminal action.

How do you take that sentence?

**A.** Well, --

MR. FITZSIMMONS: Judge, I'd like to lodge an objection. This is a doctor who's now providing us with legal opinions of legislation. It's outside the scope of his expertise --

MS. MAINIGI: Your Honor, Dr. Deer discussed --

MR. FITZSIMMONS: -- as the question was phrased.

MS. MAINIGI: I'm sorry.

MR. FITZSIMMONS: As the question was phrased.

MS. MAINIGI: I can rephrase, Your Honor, but Dr. Deer discussed the Intractable Pain Act.

THE COURT: I'll sustain the objection. You can

try another way, Ms. Mainigi.

MS. MAINIGI: Sure.

BY MS. MAINIGI:

**Q.** To your understanding, Dr. Deer, -- well, let's step back. Did you look at the 1998 Intractable Pain Act as part of formulating your expert opinion?

**A.** I did.

**Q.** And did you have an understanding of the Intractable Pain Act in the time period in which this act was passed in the course of your normal practice?

**A.** I did.

**Q.** And you went back and reviewed the Intractable Pain Act as part of putting your report together?

**A.** That's correct.

**Q.** And you've relied on the Intractable Pain Act in formulating your opinions?

**A.** One of the things I relied on.

**Q.** This last sentence that, that we've referred to, did you form an impression in the course of formulating your opinions as to what you understood that last sentence to mean?

**A.** The last sentence, in my opinion, means that the doctor didn't have to follow the guidelines, whatever the guidelines were, and still may not get in any trouble because I think the board was saying the guidelines had not

caught up with current treatment standard of care. This was how I took it at the time.

**Q.** Do you understand -- do you have an understanding of what motivated the passage of the Intractable Pain Act?

**A.** I think many factors including, you know, the, the overall thought process throughout West Virginia and the country that patients had the right to be treated for chronic pain. And intractable pain, which was severer pain, was the highlight of that focus.

**Q.** Let's go back to your chart, Dr. Deer. Should we go ahead and add the Intractable Pain Act to your chart?

**A.** I think it is a factor.

**Q.** Now, let me show you next from West Virginia in 2001 something called the Joint Policy Statement on Pain Management at the End of Life. And that is 02413.

What was this Joint Policy Statement? Let's start with this. Who was issuing this Joint Policy Statement?

**A.** It was the West Virginia Boards of Examiners of Registered Professional Nurses, Medicine, Osteopathy, and Pharmacy.

**Q.** And is there a date on the document that we see?

**A.** I don't see the date.

**Q.** I think if you turn to --

**A.** There we go.

**Q.** -- the last page.

**A.** January through March. It was approved January through March of 2001.

**Q.** And is this a statement you were familiar with at the time the statement came out?

**A.** Yes, it was.

**Q.** And is this a statement that you reviewed again in the course of formulating your opinions here today?

**A.** Yes, I did.

MS. MAINIGI: Your Honor, at this time I'd like to move to admit 02413 into evidence.

THE COURT: Is there any objection?

MR. FITZSIMMONS: No objection, Your Honor.

THE COURT: It's admitted.

BY MS. MAINIGI:

**Q.** So let's take a look at a few portions of this policy statement from the various boards in West Virginia.

If we turn to the second page, there is a heading entitled "Management of Pain."

Now, I'm going to ask you to focus on the highlighted sections. What do the highlighted portions of this document tell doctors about the role of opioids in pain management?

**A.** Well, it tells them, first of all, you have to assess whether someone is in pain, which I think is smart. You should always do that. You need to treat it promptly.

And then, and then it goes from there to the need to recognize if someone becomes tolerant.

And for the Court, tolerance means you need more of anything to get the same effect. That's tolerance.

And physically dependent, which means that if you quit taking something, you have symptoms of withdrawal. And that that happens with every opioid patient over time, and that that has nothing to do with addiction which is abnormal behavior to get a drug.

THE COURT: Doctor, let me ask you a question.

What's the difference between physical dependence and addiction?

THE WITNESS: So physical dependence means if you're taking a medication -- like say, for example, someone who took Xanax at bedtime for anxiety and they quit taking the medication and they had a seizure or they felt sweaty and felt bad, that's physical dependence. The body is used to that. The receptors are full of that drug. And when the drug is gone, they, they feel the physical effects of it.

They're not -- once they get through that, that phase, they don't crave the drug. So that means they were dependent upon it physically, but they didn't have an abnormal craving unrelated to a medical issue.

If they're addicted to Xanax like, unfortunately, many high school students have become, they take it for reasons

other than anxiety. They take it for reasons like to get high.

And when they, when they quit taking it, they crave it. They're not -- because they're in withdrawal. They crave it because they need it psychologically. And they would steal, rob, break into your house, do whatever they can do to get the drug.

THE COURT: Thank you, sir.

THE WITNESS: Yes.

BY MS. MAINIGI:

**Q.** And, so, the, the last sentence that's highlighted, what do you take that to mean, Dr. Deer?

**A.** Let me read it first to refresh myself.

(Pause)

So it's saying that governmental policies that were intended for -- to stop diversion of drugs should not interfere with the doctor prescribing medications at the end of life.

So, therefore, you would maybe prescribe medicines you wouldn't normally prescribe in that patient because they're in a terminal condition either at their home or in a hospice.

**Q.** Okay. Now I'm going to ask you to take a look at another policy statement, this time just from the West Virginia Board of Medicine related to the use of opioids in

treating other types of pain. This is from 2005. So it is MC-WV-1218. This document was already admitted under Dr. Waller.

So this policy statement, Dr. Deer, does this -- does it limit itself to a particular circumstance, the policy for the use of controlled substances for the treatment of pain?

**A.** I believe this policy was about non-cancer pain as well as cancer pain.

**Q.** And who issued this policy statement?

**A.** The Board of Medicine.

**Q.** Was this -- I'm sorry.

**A.** In West Virginia.

**Q.** Would this policy statement have been distributed to doctors in West Virginia?

**A.** Yes. If you had a license to practice medicine here, whether you lived here or outside the State of West Virginia, you would have received this newsletter.

**Q.** So if we take a look at the first page and the last sentence of the first paragraph, what types of pain treatment did the board define as inappropriate treatment of pain?

**A.** So this, this board recommendation told doctors that if you had a patient complain of pain and you didn't treat their pain or if you didn't treat them enough, if you were under-treating their pain, or if you over-treated their

pain, or if you offered them ineffective treatment that you kept doing over and over again, all of those were forms of inappropriate treatment.

**Q.** And if you look at the last paragraph on the first page, and I think the last sentence that starts with "as such," so the, the inappropriate treatment of pain included under-treatment; is that correct?

**A.** That's correct.

**Q.** And, so, what do you take from this last sentence about board action?

**A.** So in '97 we talked about the board saying you can give more medication without fear if you document the select patient. And here the board said if you under-treat with opioids, basically you would be investigated. And it led to many complaints at that time against doctors for under-treatment of pain.

**Q.** In your experience here in West Virginia during this time period, was this a real concern for physicians being investigated for the under-treatment of pain?

**A.** It was for some, I mean certainly not for all, but it was for some. In fact, I was, as I said earlier, asked sometimes to comment in a hospital about someone under-treating someone and to review a chart and give an opinion.

**Q.** Now, let's flip over to the second page, Dr. Deer,

please, and that first sentence at the top of that page. What do you understand the board to be saying there?

**A.** That the board recognized that opioids, controlled substances, may be essential to treat both acute pain, so when you break your leg or fall off a scaffolding; after surgery, so when you have your appendix removed; chronic pain, which we've defined, whether due to cancer or non-cancer origins.

**Q.** So the board was saying that opioids were essentially appropriate for the treatment of all kinds of pain?

**A.** It was basically a reinforcement of the 1997 statement expanding a bit to include all types of pain.

MS. MAINIGI: Now, Matt, if we can come back to the chart.

BY MR. FITZSIMMONS:

**Q.** Dr. Deer, can we go ahead and add this 2005 Board of Medicine policy statement to the chart?

**A.** I believe that we would, yes.

**Q.** Now, we've been focusing on actions from the Board of Medicine and other boards from West Virginia from '97, 2001, and 2005.

To your understanding and knowledge, was West Virginia the only Board of Medicine in the country that was issuing guidelines and policies like this at the time?

**A.** No, not at all.

**Q.** What did you understand was happening in the rest of the country?

**A.** Well, so there was a, a group called the Federation of State Medical Boards that gave advice to medical boards around the country. And many of those boards adopted those recommendations. So I think West Virginia was, along with many other boards, creating the same types of policies.

**Q.** And the guidelines from the Federation of State Medical Boards just -- those also have an impact on physician prescribing in West Virginia?

**A.** They do in West Virginia for sure because certainly some of the, some of the materials that the Federation of State Medical Boards published were given to West Virginia physicians.

**Q.** And how do you know that?

**A.** Because I received a copy of the book Dr. Fishman wrote as part of that process of Federation of State Medical Boards.

**Q.** And we'll come back to Dr. Fishman's book in a second.

Now, in the binder, then, I think, just for the purpose of the record, I think the Federation model guidelines were covered with Dr. Gilligan who was here on Friday. So we're going to skip over those with you. But those are, for the purpose of the record, 02937 and 03605.

So let's stick with the West Virginia Board of Medicine

in 2005. And I'm going to ask you to look at 3010. And it's another West Virginia Board of Medicine quarterly newsletter.

And I'm going to ask you to turn to Page 5 of this newsletter, please.

Page 5 of this newsletter is a letter to the head of the DEA from, among other Attorney Generals, the Attorney General of the State of West Virginia, Darrel McGraw. There are multiple Attorney Generals that sent a letter to the head of the DEA.

Have you had a chance to review this letter?

**A.** Yes, I have.

**Q.** What is your understanding of the gist of the letter?

**A.** Well, so they write a letter to Ms. Tandy who I had the chance to meet. She was the Director of the DEA under President Bush.

MR. FITZSIMMONS: Judge, I'm going to lodge an objection as to him interpreting the Attorney General's letter as to what it means to him.

MS. MAINIGI: Your Honor, I think it was notice to him and other doctors in West Virginia because the letter was published in the Board of Medicine newsletter which went to all licensed physicians in West Virginia. They received the newsletter and had an opportunity to review the letter that the AG sent to the DEA and interpret the meaning of the

letter.

THE COURT: Can't he testify as to what -- his understanding of what the, what the letter meant to him, Mr. Fitzsimmons?

MR. FITZSIMMONS: It's hearsay, Judge, for him to get up here and interpret that this is -- it's hearsay. It's an out-of-court declaration that's being offered at this time. She said notice but it's for the truth as to what's in there.

MS. MAINIGI: Your Honor, --

MR. FITZSIMMONS: It's improper.

MS. MAINIGI: I'm sorry. Go ahead.

MR. FITZSIMMONS: I think that's totally improper, Your Honor.

MS. MAINIGI: Your Honor, it is not offered for the truth of the statement at this point. It is purely offered as notice, as many of these documents were that came in through Dr. Gilligan and many other experts here, of notice to the healthcare community of what was happening in, in the world, essentially, in their location with respect to the standard of care.

I also think under 902(5) this newsletter is a publication that's issued by a public authority and is self-authenticating. So I think the authenticity is established. But hearsay -- this is being offered purely

for notice, Your Honor. And it is also expert reliance materials, Your Honor.

THE COURT: Well, 902 just authenticates it. It doesn't get around the hearsay problem if I understand it.

MS. MAINIGI: No. And on the hearsay issue, Your Honor, it's just notice to the healthcare community. And it is part of the reliance materials that Dr. Deer relied upon.

THE COURT: Well, I'll let him testify as to what it is and who it was sent to if he knows. Beyond that, I'll sustain the objection.

BY MS. MAINIGI:

**Q.** Dr. Deer, what is your understanding of the gist of the letter from the Attorney General of West Virginia to the head of the DEA?

**A.** So --

MR. FITZSIMMONS: I'm going to object. I think that's the same exact question I objected to.

THE COURT: Yeah. I'll sustain the objection to that question.

MS. MAINIGI: Your Honor, then I misunderstood what you were going to let him testify to. Could you repeat that, please?

THE COURT: Well, maybe I made myself unclear. But I think he can testify as to what it is and who it was sent to and that's about it, what his understanding of the

purpose of it was.

MS. MAINIGI: Thank you, Your Honor.

THE COURT: But don't get into the substance because I think the substance is hearsay.

MS. MAINIGI: Okay. Thank you, Your Honor, for that clarification.

BY MS. MAINIGI:

**Q.** Dr. Deer, could you tell us what your understanding was of the purpose of the letter?

**A.** Yes. The purpose was to communicate to the DEA concerns of the Attorney Generals around the country about opioid prescribing and limitations therefore.

**Q.** And, specifically, what about opioid prescribing and limitations?

**A.** That was a concern. They felt the state had the same responsibility to oversee it and the federal government was overseeing it, and there was communication about who should be overseeing it.

**Q.** And the -- did the Attorneys General express a view as to what the DEA should be doing?

**A.** They felt that the shift was more towards anti-diversion and it should be more towards treatment.

**Q.** Thank you. Let's see.

MS. MAINIGI: Your Honor, at this time I would like to move for the admission of 3010 into evidence.

THE COURT: Which one is that?

MS. MAINIGI: It's the newsletter that we've been talking about, Your Honor, and the --

THE COURT: I've got that.

Do you have any objection to that, Mr. Fitzsimmons?

MR. FITZSIMMONS: Judge, I believe you sustained the objection I had previously made.

THE COURT: Well, I think I did.

MS. MAINIGI: The objection was sustained, Your Honor, as I understood it, as to the question. But news letters like this were actually introduced into evidence with Dr. Waller, for example, as well as several other witnesses and --

THE COURT: Well, it comes in for the limited purpose of notice but not for the truth. Is that right?

MS. MAINIGI: That's correct.

THE COURT: Well, I'll admit it for the limited purpose.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** So we talked earlier about the 1998 Intractable Pain Act. Do you recall that, Dr. Deer?

**A.** I do.

**Q.** And do you recall that in 2009 the West Virginia legislature amended the Intractable Pain Act?

**A.** I do.

**Q.** Let me ask you to take a look at 3067 which is the 2009 Management of Pain Act. Are you familiar with that act, Dr. Deer?

**A.** Yes, I am.

**Q.** And did you rely on that act in the course of forming your opinions here today?

**A.** I did.

**Q.** And were you familiar with the act at the time it was passed in 2009?

**A.** I was.

MS. MAINIGI: Your Honor, I'd like the Court -- to ask the Court to take judicial notice of 03067.

THE COURT: Any objection?

MR. FARRELL: Not to you taking judicial notice, Judge.

I would like to place on the record, aside from the examination of this witness, that the subject of some of these questions was the subject of motions *in limine* and *Daubert* motions by the defendants prior to trial.

And, in fact, you struck one of our expert witnesses from the DEA who was going to testify about the Controlled Substances Act.

So I would just like to note my continued objection to witnesses in this court being served as legal experts.

MS. MAINIGI: Your Honor, --

THE COURT: Well, --

MS. MAINIGI: -- we don't agree with that statement. This is a -- this is a standard of care expert. And these acts in West Virginia obviously served the purpose of modifying the standard of care for West Virginia physicians, of which Dr. Deer is one.

THE COURT: The 03067 is judicially noticed and admitted.

BY MS. MAINIGI:

**Q.** Dr. Deer, if you'd take a look at the top of that document that references the act. It says "an act" and then it goes on to describe it.

Can you just basically explain to us what your understanding is of what the legislature did here?

MR. FITZSIMMONS: Judge, I'm going to object to him giving legal opinions as to the legislature.

MS. MAINIGI: Your Honor, he's doing this from his point of view as an expert on standard of care and a West Virginia treating physician who had to at the time interpret what the legislature was doing vis-à-vis this act.

THE COURT: I'll overrule the objection. I think he can refer to it as a basis for his expert opinion. Go ahead.

THE WITNESS: They took the word "intractable" out

of the previous legislation. We updated it with the word -- just chronic pain. So they made it easier to treat patients who didn't have severe pain.

BY MS. MAINIGI:

**Q.** Was the '98 legislation related or limited to intractable pain?

**A.** That's correct.

**Q.** And this 2009 legislation was amended to apply to all pain?

**A.** They took the word "intractable" out of this legislation.

THE COURT: Yeah. I think this is admissible. He's -- his testimony is the course of the changes of the standard of care over time and I think that his testimony here is relevant to that. So the objection is overruled.

MS. MAINIGI: Thank you, Your Honor.

And just for the purpose of the record, to respond to Mr. Farrell's objection further, I'll just note for the record that, as we know, there were a number of company witnesses that were called by the plaintiffs to come and testify in this matter.

And the plaintiffs, in the course of all of that testimony, elicited a number of -- posed a number of questions and elicited testimony about those individual lay person witnesses' understanding of DEA regulations as well

as the CSA.

BY MS. MAINIGI:

**Q.** You can put that document away, Dr. Deer.

And let's take a look at another joint statement issued in 2010. And that is 2414.

We had earlier looked at a 2001 joint statement on pain management from a number of boards in West Virginia; right?

**A.** Correct.

**Q.** Okay. And in 2010 there seems to be a reissuance of the 2001 joint statement. If you go to Page 4 of 2414, what is the date of the adoption?

**A.** March 12, 2001, initially but re-adopted May 10th, 2010.

**Q.** And are you familiar with this 2010 joint policy statement, the re-adoption of the 2001 statement?

**A.** Yes, I am.

**Q.** To your understanding, did this re-adoption encourage or discourage prescribing of opioids?

**A.** It encouraged prescribing of opioids.

MS. MAINIGI: Your Honor, just, just as the earlier joint policy statement was admitted, I'd like to move for the admission of 2414, please.

THE COURT: Any objection to this one?

MR. FITZSIMMONS: No objection, Judge.

THE COURT: It's admitted.

BY MS. MAINIGI:

**Q.** Let's go back to our chart, Dr. Deer. And in your chart would you add the 2009 Management of Pain Act as well as the 2010 joint policy statement?

**A.** I would.

**Q.** So, Dr. Deer, we've looked at a number of, of statements and policies and acts from West Virginia. Do you have an opinion on the relationship between the standard of care for prescribing opioids for the treatment of pain and all of the West Virginia laws and policies that we've been discussing?

**A.** I think there's no doubt that the things on our graph to the board changed the standard of care in West Virginia.

**Q.** In what manner?

**A.** It led to increased opioid prescribing around the state.

**Q.** And do you have an opinion on whether West Virginia prescribers, in fact, prescribed opioid medications more freely in accordance with the guidance that was issued by the various bodies in West Virginia?

**A.** I felt certain they did. And I saw it personally in the referral base that we have. As those acts became law, we saw patients getting sent to us with more and more opioids.

**Q.** And do you have an opinion on whether doctors who in

accordance with this guidance issued in West Virginia, those doctors who more freely prescribed opioid medications to their patients, were they acting reasonably based on the information available to them at the time?

**A.** I think at the time, the vast majority of those doctors were acting within reasonable medical standards and standard of care.

**Q.** And does that include the doctors who formed your referral base, so the family doctors that referred patients to you at the time?

**A.** I would say that the family doctors referred to me and followed along those guides and treated patients with high-dose opioids sometimes for many years before they sent someone to see me because that was the tools they understood at that time.

**Q.** Now, you, you referenced Dr. Fishman earlier. And one thing we've not discussed yet is physician education.

Do you have an opinion as to whether physician education played a role in the standard of care for pain treatment?

**A.** So physician education -- and it's something called continuing -- for the Court, continuing medical education is something we all have to do to keep our license updated.

So every physician has to undergo continuing education. And part of that required education in West Virginia became

education on pain. So it definitely made an impact overall as we got near 2010.

**Q.** Now, did Dr. Fishman teach at various continuing medical education events in West Virginia, to your knowledge?

**A.** He taught in person at a state medical association sponsored seminar on pain. And he also taught via video because every doctor in West Virginia at one point had to watch his lecture to recertify their license.

**Q.** And are you familiar with Dr. Fishman's book, Responsible Opioid Prescribing?

**A.** I am.

MS. MAINIGI: And I believe, Your Honor, just for the purpose of the record, this book was admitted during Dr. Waller's testimony and is 02111.

BY MS. MAINIGI:

**Q.** Was this book disseminated to doctors in West Virginia?

**A.** It was.

**Q.** And did the West Virginia -- in addition to inviting Dr. Fishman to come speak in West Virginia, did the West Virginia Board of Medicine promote Dr. Fishman's teachings in both -- essentially into early 2010?

**A.** At that time, based on my recollection, in order to renew yourself, you had to receive a lecture from

Dr. Fishman on opioid prescribing, a lecture from me on procedures. I think there was a third lecture. I can't remember what that was. I think it was three hours of CME and I can't recall the third lecture. But you had to go on-line and watch that or go to an in-person event.

**Q.** And do you have an opinion on the impact that, that the CMEs that Dr. Fishman and others were involved with, what impact that had on doctors in West Virginia regarding the prescribing of opioids?

**A.** CME impacts your -- based on the evidence provided by the speaker. So, you know, I think any CME that's well done is going to be impactful based on the evidence that that person chooses to present.

**Q.** And, again, doctors who prescribed in accordance with the standard of care articulated at these CMEs and in Dr. Fishman's book, in your opinion were they acting reasonably in light of the information available to them at the time?

**A.** At the time of that decision-making process from the physician, yes.

**Q.** Now, I want to shift over to demographics in West Virginia, Dr. Deer.

Do you have an opinion on whether demographics in West Virginia had an effect at which -- had an effect on the rate at which opioids were prescribed by West Virginia

physicians?

**A.** I believe that it had a large impact on prescribing in West Virginia versus other places.

**Q.** And did you assist us in preparing a slide that summarized those factors?

**A.** I did.

MS. MAINIGI: Matt, if we could put that on the screen, please.

BY MS. MAINIGI:

**Q.** Were these the factors you noted in your report and on the slide?

**A.** I think those are all the factors but one.

**Q.** Well, let's go through the, the factors.

What do you mean that higher rates of chronic pain had an effect on higher opioid prescribing in West Virginia?

**A.** If you look at the demographic data, West Virginians have more arthritis than any other state I believe. We have -- I think we're third in obesity, and obesity has been linked very closely to chronic pain.

For example, if you gain four pounds -- if you gain one pound, it puts four pounds of weight on your spine and your knees and your hips. So it's important.

We also have a higher rate of chronic pain among smokers with vascular disease.

So there are many factors that leads to our chronic

pain rate being higher. We'll get to some of other ones over the next three bullet points we have here.

**Q.** And -- well, let's, let's move to the second. Tell me about the older population in West Virginia and how that contributes to higher opioid prescribing.

**A.** Well, we're on average four years older than other states. We have young people like Mike there that's leaving the state for jobs and old people staying. And we have a death rate that's greater than the birth rate so -- less than the birth rate.

So we're, we're older. We're getting older. And if you look at data, the older population has a higher risk of chronic pain diseases.

**Q.** And then your, your third example is that there are more injuries with more workers in physically demanding jobs in West Virginia which also leads to higher opioid prescribing. Explain that.

**A.** Well, we're a tough group of people in West Virginia, you know. And back in the days from '94 to probably about 2008, we had a lot of coal miners being injured. We don't have as many now, unfortunately for jobs. But we also had timbering and plants and construction.

So we have a, we have a blue collar work force that works really hard. And if you look at the data on that, they get injured more than physicians and attorneys get

injured and need treatment. And many times they were treated with opioids.

**Q.** And the last factor you list is insurance policies. Can you explain what you mean by that?

**A.** Well, again, many physicians that are specialists don't accept West Virginia Medicaid. I do. I grew up with not much money, so I always feel it's my need to take care of everyone.

And a lot of times we can't get approval for innovative therapies because of the budget of Medicaid, and other insurers too, Workers' Compensation, you know, public employees. Sometimes it's limited to what you can do and I think that sometimes led to a denial of referral to a specialist, whether it be a pain specialist or a neurosurgeon. And that, that patient stayed in the primary care specialist's office on medication. So I think all these factors played a role.

**Q.** And, so, how did that translate into West Virginia -- West Virginia residents perhaps having a higher rate of opioid prescribing?

**A.** I think all those factors together led the primary care specialists particularly to start people on opioids. And then they stayed on those medications sometimes for life once they were on them.

**Q.** Thank you, Dr. Deer. We can take that down.

Now, we spent a long time on your first phase. Let's shift over to the second phase of the standard of care that you mentioned earlier in your overview.

Just remind us briefly what the second phase is.

**A.** So I think in 2010 we started seeing a real peak in people on high doses of opioids in the state. I know that personally because they were sent to see me and I accepted them as patients. So it got pretty bad.

And we also had a need to I think determine what a pain clinic was. So around 2011 we started seeing changes to try to turn the situation back towards therapies other than opioids.

**Q.** And I think you referred to the second phase as balancing. Explain that to us.

**A.** Well, I think the pendulum has swung so far to the pro-opioid side by physicians' prescribing habits that it became very, very difficult to understand what to do with some of these patients who still were in severe pain despite high-dose opioids.

So there was a movement by I think several parties to try to figure out ways to allow treatment but be more balanced and try to think of ways to use other therapies other than opioids. So -- and to control better how those were prescribed.

**Q.** Now, in 2012 there was legislation passed called the

CSMP and Chronic Pain Clinic Licensing Act. Are you familiar with that legislation?

**A.** Yes, I am.

**Q.** Okay. And did you tell us earlier that you served on a committee related to the CSMP?

**A.** I did.

**Q.** And was that a committee associated with this legislation?

**A.** It was.

**Q.** Let me ask you to take a look at 03105.

MS. MAINIGI: And for the purpose of the record, this is Senate Bill 437 which was actually admitted during Dr. Gupta's testimony.

BY MS. MAINIGI:

**Q.** Now, did this law impose new requirements on doctors?

**A.** It did.

**Q.** If you take a look at Page 19 of the act, do you see the heading -- and 19, just for everybody's benefit, I'm going by the page numbers on the lower left.

MS. MAINIGI: And if we could focus on the very bottom of Page 19, Matt.

BY MS. MAINIGI:

**Q.** So is one of the things this act did, Dr. Deer, did it require doctors to check the Controlled Substances

Monitoring Program before prescribing opioids to certain patients?

**A.** It did.

**Q.** And did that requirement exist before this law was passed?

**A.** There was no requirement before this law was passed.

**Q.** And what did that help with if a doctor was consulting and, and by law was told to consult the CSMP before prescribing opioids?

**A.** I think it really helped with doctor-shopping, if you will, because if they were receiving medication from other doctors and the doctor had to check that data bank, they saw that before they prescribed a controlled substance. So it helped with the issue if patients went to multiple doctors for the same type of drug.

**Q.** So did that mean, as a hypothetical, a patient who went to see three different physicians and got controlled substances prescriptions from all three physicians, that that patient may not be able to do that anymore since these doctors were required to check the CSMP?

**A.** Well, it certainly -- the first person may not have seen it, but the next two should have seen it if it was reported by the pharmacy who filled the prescription to the pharmacy board.

**Q.** And the act did a couple of other things too.

If you turn to the prior page, Page 18 at the very bottom, there's a reference at the bottom to the Review Committee making determinations on a case by case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system for abnormal or unusual usage patterns of controlled substances.

What is your understanding of what this act required in this regard?

**A.** It required the Board of Pharmacy to create a committee to look at abnormal prescribing by doctors.

**Q.** And what was the committee looking for?

**A.** People that were outliers and the amount of medicine to individuals, as well as people who were prescribing to -- you know, people that were actually in the same family. They were looking at people who had deaths. The medical examiner was part of this committee. So if there was a death and there was a high prescriber with a lot of death rates, those sort of issues.

**Q.** And what would -- would there be contact made with some of the doctors who were reviewed? What would happen?

**A.** So, as I said earlier, Mr. Goff ran that committee that I was on. So we reviewed every two months all the data. So if a doctor had a death and they were prescribing a controlled substance to that patient, they received a letter from our committee that they needed to review their

prescribing habits.

We didn't say they caused their death, but it certainly let them know that we were aware of the death and we wanted them to look. And, of course, some doctors received multiple of those letters, you know. And, certainly, that was a big issue for the Board of Pharmacy Oversight Committee.

Then they looked at were people prescribing multiple classes of drugs to the same person because that can also be an issue.

And then people that had more than five doctors prescribing to them, all those doctors received a letter from this committee saying that you have a patient -- they should have seen it themselves from the Board of Pharmacy check. But they got a letter saying you have a patient who's seeing more than three physicians for a controlled substance and they were asked to review their chart.

So it was all informational to them initially what was going on in their practice in case they were in need of education.

**Q.** And, so, the CSMP, coming back to that database for a moment, the CSMP database was accessible by physicians; is that right?

**A.** Every time you see a patient, you could access that with your password of what the patient had received from

other physicians and from yourself.

**Q.** But the general public could not access the CSMP?

**A.** I think that would be a HIPAA violation for the general public to access what a patient was given.

**Q.** And the third thing this act did -- I think you referred to it earlier, Dr. Deer -- is there were provisions in the act related to pain management clinics. Do you recall that?

**A.** I do.

**Q.** And what do you understand the act to include with respect to pain management clinics?

**A.** So there were people who were family doctors calling themselves a pain clinic who had no training. And if they were prescribing more than 51 percent of their patients a controlled substance, then they would fall under this act.

And what that led to -- and, again, I remember the committee that helped draft this law. They would go out and be certified then. And they had many things they had to meet as a criteria. It was really a way to get better control of some of these centers that were really not doing the right types of therapy for patients.

**Q.** So was there a licensing requirement and an inspection requirement?

**A.** If you had over 51 percent of your patients on a controlled substance, that was true. If you didn't meet

that criteria, you were excluded from that. But physicians who had more than 51 percent of their patients receiving a controlled substance were inspected and were either licensed or told to desist in their treatment.

**Q.** So these three elements of the 2012 act, to your understanding, what was the intended effect of these new requirements?

**A.** It was to, I believe, to look at the prescribing habits of physicians to try to get a handle on who actually was treating pain in a more exact fashion and a more appropriate way. So that was kind of the main gist of this act I believe.

**Q.** And was there -- now, this act, did it limit in any way the amount of opioids a physician could prescribe?

**A.** It didn't limit the amount at all. It was a first step, though, I think toward the balancing as I talked about.

So, you know, in '11 the secession began. In '12 this happened. That was the first step. It was a good step towards improving things. It still didn't limit the doses that people could prescribe to patients without looking at other options.

MS. MAINIGI: Matt, if we could put our chart back up.

BY MS. MAINIGI:

**Q.** And, Dr. Deer, should we add this 2012 legislation to your chart?

**A.** I would.

**Q.** Now, third phase of the standard of care that you referenced, you said that was approximately 2015 to today. Can you just again briefly describe that phase for us?

**A.** So I think this is the most important phase as far as a solution to this issue. It's the phase where we had a number of parties trying to better define the balance of prescribing versus abuse and addiction. So -- and who would really be proper in looking at, again, updates on evidence of what really actually worked instead of the conservatism of opioid prescribing which has been impactful to the standard of care, and I think it resulted in that downward curve. I know that from looking at this curve also in my own experience.

**Q.** So we've mentioned a couple of times the 2015 CDC guidelines. Those are at 02523. Those have been admitted through Dr. Gupta.

If you could take a look at those, are those, in fact, the 2016 CDC guidelines?

**A.** Those are the CDC guidelines from 2016.

**Q.** And did these guidelines make recommendations about how doctors should limit the quantity of opioid medications they prescribe to patients?

**A.** It talked about both quantity and dose.

**Q.** To your understanding, were these the first guidelines from the federal government that told doctors they should carefully reassess evidence of individual benefits and risks when increasing dosage above daily thresholds?

**A.** I believe that it is.

**Q.** And were they the first federal guidelines that told doctors treating acute pain that they could generally limit prescriptions to a several-day supply, I think a three-day supply?

**A.** I believe that it was.

**Q.** And I think you testified earlier that your committee put together the SEMP guidelines partly in reaction to the CDC guidelines coming out. Is that fair?

**A.** The CDC gave West Virginia a grant to create that committee to -- you know, this is a guideline but it doesn't really tell a primary care doctor what to do for example.

This was intended -- it says in this guideline for primary care, although I feel like it applies to everyone because it's good guidance. I think the CDC did a very good job. Some people haven't liked this guidance, thought it was too restricting. But I think it was very good.

And, so, the SEMP guidelines then were really created to give a play book to doctors in West Virginia on, okay, if you're going to do what the CDC says, how do you achieve

that?

So I think that was meant to be really a supplement to CDC for our state particularly. And a few other states adopted our SEMP guidelines as well. I know Arizona did. There are pain societies and others.

**Q.** And, and I -- just for your benefit, if you need them, Dr. Deer, the SEMP guidelines are at the very front of your binder and they are 3036 and are admitted. They were also released in 2016; right?

**A.** That's right. I believe this was -- March was the CDC and I think the SEMP was October I believe.

**Q.** And did the CDC and SEMP guidelines encourage doctors to caution basically now when prescribing opioids?

**A.** I think the CDC gave doctors a play book on amounts and dosing. And I think SEMP gave doctors a play book on what to do instead of opioids when possible.

**Q.** And to your knowledge, do doctors in West Virginia rely on both the CDC guidelines from 2016 as well as the SEMP guidelines from 2016?

**A.** I think it had a major impact on prescribing.

**Q.** And how do you know that?

**A.** Because, again, like I said earlier, back from '97 to 2015 or '16 I was receiving patients on more and more controlled substances referred to me and my partners. And we would spend time trying to find solutions.

And after these two documents came out, we started to see a decline in that. The amounts were less. The doses were less. So -- and people were sending patients earlier to see us. They didn't wait five years after back surgery. They waited three months after back surgery.

So I saw a shift in both the amount of drugs and the time line of when people got sent to see us. But, again, it was after these two, two major pieces of information were given to physicians.

**Q.** And, so, is it your opinion, Dr. Deer, that the 2016 CDC guidelines as well as the SEMP guidelines had a role in changing the standard of care in West Virginia?

**A.** I think they had major positive impacts in changing the standard of care in West Virginia.

MS. MAINIGI: So let's come back to our chart, Matt.

BY MS. MAINIGI:

**Q.** And, Dr. Deer, should we add the CDC guidance as well as the SEMP guidelines to your chart?

**A.** Absolutely.

**Q.** Now, following on 2016 as we see distributions going down in that time period, did the West Virginia legislature pass any other legislation related to opioid prescribing?

**A.** In 2018 the West Virginia legislature passed new legislation.

**Q.** And what was that called?

**A.** I don't remember the name exactly of the bill, but it was a bill about really proper prescribing of opioids.

**Q.** And just -- I will ask you to take a look at 3054. And does that refresh your recollection as to what it was called?

**A.** It does, the Opioid Reduction Act. It seemed too obvious to be the real name of the bill, but I think that was it.

MS. MAINIGI: Your Honor, I ask the Court to take judicial notice of the Opioid Reduction Act, 3054.

THE COURT: Any objection?

MR. FITZSIMMONS: No objection.

THE COURT: It's noticed and admitted.

BY MS. MAINIGI:

**Q.** Now, if you turn to Page 3 of this document, I think it's 16-54-4. And under Subsection (e) --

MS. MAINIGI: If we could blow that up, Matt.

BY MS. MAINIGI:

**Q.** And that section is entitled "Opioid Prescription Limitations." And can you describe to us what (e) says?

**A.** Yes. It really says -- it gives a guidance for doctors. ER, four days of opioids for an injury; no more than four days if you're in an outpatient setting with Schedule II opioids, no more than four-day supply.

And if you decided that someone should be treated for pain, no more than a three-day supply as an outpatient. And then dentists and optometrists could only -- could not issue more than a three-day supply after surgery.

And then lastly, as you've highlighted here, a practitioner other than a dentist or optometrist could only give a seven-day supply, the lowest effective dose which in the medical judgment of practitioner would be best in the course of treatment for his or her condition.

So it really limited when someone come to you complaining of pain how much medication you could give either emergently, acutely, or after a procedure, for example.

**Q.** And was -- to your knowledge, was this type of legislation being passed in other states as well?

**A.** It was.

**Q.** So let me ask you to look a bit further down on Page 3 at (g). Did that provision, Dr. Deer, limit doctors to prescribing only a thirty-day supply of opioids with two more thirty-day refills if that doctor checked the CSMP database?

**A.** That's correct. It required them to give only that first month. And then they could give two additional prescriptions after that. And they had to check along that time the data bank to see if they were getting other

prescriptions.

**Q.** And was this the first time the state had imposed an objective limit on how many opioid medications doctors could prescribe?

**A.** Yes, because there were doctors who would previously write three months of prescriptions for someone in high doses and say, "See me in three months," and send them home with that. And that was not uncommon, particularly in southern West Virginia.

So this said you can't do that. You have to reassess the patient, make sure they still need the prescription. So I think this was a very helpful piece of legislation.

**Q.** And if you turn to Page 5 under 16-54-5, subsequent prescriptions and limitations, do you see that the act required doctors to inform patients about alternatives to opioid medications and the risks associated with opioid medications before prescribing them?

**A.** Yes. I think both those were very important. The risk had to be at least noted that this could be addictive and could cause side effects. But also they had to tell them other alternatives, whether it be injections, devices, physical therapy. Before this act, they never had to mention anything but medication to the patient.

**Q.** So to your understanding, what was the intended effect of this legislation on inappropriate opioid prescribing?

**A.** I think the CDC was helpful, but it didn't go far enough as far as some of the problems we've seen. And I think this lent doctors some guidance on how to do a better job of really prescribing more judiciously initially because as I said earlier, once someone chronically has been on a medication, it's very difficult to reduce it or limit it.

So this is looking at the initiation of opioid therapies somewhat and I think that's where my advice has been for some time.

MS. MAINIGI: Matt, if we could go back to the chart.

BY MS. MAINIGI:

**Q.** Should we add the 2018 West Virginia Opioid Reduction Act?

**A.** It is a major factor in changing the standard of care in West Virginia in a positive light.

**Q.** So these recent laws from 2012 -- and guidelines from 2012, 2016 and 2018, have they together resulted in a change of the standard of care in West Virginia?

**A.** I think the data shows there's no doubt about that.

**Q.** And did any of those requirements exist before 2011?

**A.** No. I think the '12 act was written based on what we were seeing before '12. And there was no act before that that limited prescribing or anything else to do with opioids.

**Q.** In your opinion, Dr. Deer, do doctors in West Virginia today have the information that they need to make good decisions about prescribing opioids?

MR. FITZSIMMONS: Judge, I'm going to object to him testifying globally as to all doctors. As to anesthesiologists or people involved in his specialty, which he's certainly recognized as a specialist in pain medicine, I believe he can testify. But for him to get in here and talk about what gynecologists, obstetricians, pulmonologists and other doctors in the medical profession, I think it's far in excess of his expertise.

MS. MAINIGI: Your Honor --

THE COURT: The question was in his opinion as an expert do doctors in West Virginia today have the information that they need to make good decisions.

I'm going to overrule the objection and allow him to answer that. Now, the issues you raised I think would be appropriate for cross-examination, but I'm going to overrule the objection to that question.

MR. FITZSIMMONS: Your Honor, may I put one more thing on the record? I apologize.

THE COURT: Yes, you may, absolutely.

MR. FITZSIMMONS: In West Virginia as an expert you have to be an expert and qualify within the specialty actually that you practice. And you have to practice so

much of that time.

He's already testified he's not a primary care physician, doesn't practice in primary care. All of his practice is referral care.

So he would not qualify -- could not qualify as an expert in West Virginia to testify as an expert in anything other than anesthesiology or pain management.

THE COURT: Well, your objection will be preserved for the record, Mr. Fitzsimmons. But he is an expert in pain management and I think this generally goes to that subject. But your objection is shown on the record.

Go ahead, Ms. Mainigi.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

**Q.** Dr. Deer, are you aware whether there have, in fact, been a decrease in prescriptions for opioid medications in West Virginia since 2011?

**A.** Yes. There's been a major decrease in prescribing of controlled substances, particularly Schedule IIs.

**Q.** I'm going to ask you to turn to 850, the last document in the binder. Can you identify what this document is?

**A.** I was waiting for you to show it up on the screen. It's a West Virginia Board of Pharmacy Controlled Substance Annual Report from 2018 which I believe might be the last year recommending that, right around that time.

**Q.** And are you familiar with this report?

**A.** I'm very familiar with it.

**Q.** Is this report made available publicly to your knowledge?

**A.** I think that it is.

MS. MAINIGI: Matt, if we could put that up on the screen.

THE WITNESS: There we go.

BY MS. MAINIGI:

**Q.** Now, is the purpose of this report to outline the activities of the Board of Pharmacy in administering the CSMP?

**A.** Yes.

MS. MAINIGI: Your Honor, I would like to move for the admission of 00850.

THE COURT: Any objection?

MR. FITZSIMMONS: No objection, Judge.

THE COURT: It's admitted.

BY MS. MAINIGI:

**Q.** If you could turn to Page 4 of the document, please. Now, what does in 2018 the West Virginia Board of Pharmacy say has been the change in dispensing of hydrocodone and oxycodone since 2011?

**A.** Want me to read that portion?

It says that the opioids, Schedule II, hydrocodone and

oxycodone, have seen the most significant drop in numbers with a combined decrease of over 61 million doses since 2011 and 18 million dose increase last year alone going up to 2018. So that's in Figure 5.

**Q.** And, so, if we take a look at Figure 5 -- let's go to that -- which I think is on the next page. And that's entitled "West Virginia Opioid Drug Doses Dispensed."

So what does this chart show about the trend in dispensing hydrocodone and oxycodone?

**A.** I think it shows what we've talked about from the 2018 law, 2016 CDC, and 2016 SEMP, that the opioid prescribing for hydrocodone and oxycodone, the market has been reduced.

It also shows that buprenorphine has gone up some. And that before was used only for abuse as a drug for addiction. But now it's been approved for pain in low doses and it's thought to be less addictive because it's an antagonist, which for the Court means it actually has both pain reduction and opioid abuse reduction properties.

This mimmicks exactly -- if we go to 2011 to '18, this mimmicks exactly what we've seen. In 2011 we probably reached our peak of receiving maybe 50 to 100 patients a month that came to see us on high-dose opioids which we'd have to take over and try to manage.

And now in 2018 we're seeing very few people come to see us on high-dose opioids at all, which means we're going

to have a better chance of helping them. And it's gotten even less so I believe in the last year. We're seeing even less and less.

So I think this mirrors what I've seen personally in our practice as a referral for most of southern West Virginia. It shows that those three things that we talked about have been successful, I believe, in changing the standard of care towards a more judicial approach to opioid prescribing.

**Q.** And the three things we talked about, can you explain what you mean by that?

**A.** Yeah. The three things we talked about was the 2018 legislation which we talked about a moment ago; the SEMP guidelines which are the play book for West Virginia doctors; and the CDC guidance which gave us dosing recommendations.

**Q.** And what about the 2012 legislation?

**A.** The 2012 legislation helped us, I believe, to really establish what a pain clinic was because there were people calling themselves pain clinics who had no training, no expertise, no ability to do multi-modal therapies where you have physical therapy and other therapies available.

And I think it also gave some notice that you had to go back and check the Board of Pharmacy records. It also established the Board of Pharmacy committee which I think

really was -- in fact, some of the people that were prescribing haphazardly were found to be noted in that committee's findings.

**Q.** And let me come back to your practice which you said is an exclusively referral practice; right?

**A.** Correct.

**Q.** And is it family physicians primarily that are referring to you?

**A.** Well, so, if you look at our data from referral sources, we get referrals from everyone, you know, from surgeons who operate on someone's spine, from thoracic surgeons who have taken out a tumor from your lung, from urologists with prostate cancer, gynecologists with pelvic pain.

But the vast majority of our patients come from the family physician, probably 90 percent. Those other specialties make up, each of them, a percent or two, maybe 80 percent family practice I would say.

I think we're talking about the non-cancer population. The cancer population is a whole different bucket. Those are mostly from the oncologists, but sometimes from radiation oncologists, sometimes from family physicians.

**Q.** So from your practice, which is other physicians referring to you, do you have a pretty good sense of the prescribing patterns of other types of physicians in West

Virginia?

**A.** I think as you look at the report we've been talking about, the 2018 report, Figure 3 shows the controlled substances doses dispensed. That's a mirror image of what I've seen because as we saw that peak on that graph in 2012, that's when I saw my peak.

Everybody that came to me almost from southern West Virginia was on 100 milligrams of morphine equivalents a day or more. And we, we would then take that patient and try to do a spinal cord pacemaker or an ablation, reduce their doses.

And we were successful. But every time we got rid of some of those opioid burdens, there was a new sieve of people coming in who were on the same dosage. Right? So we kept seeing it get refilled.

After 2015-'16 it started to decrease. After '18, the legislation we talked about. Most people that come to see me now are on no opioids or very little except for my cancer patients.

The reason that's important -- I just published a new study with the Mayo Clinic on combined patient population. We showed our devices work better in lower dose with no opioids. So our chances are better now than they were before of helping you.

So I think we've seen a real shift and I've seen it

personally in my own prescribing habits because I take over what I can.

**Q.** Okay. So just to summarize now what we've been talking about for the last few hours, Dr. Deer, in your opinion, has the standard of care for the prescription of opioids changed over time?

**A.** It's been quite a journey and it's changed dramatically over time in different directions.

**Q.** And has that changing standard of care affected the rate at which doctors prescribe opioids in West Virginia over time?

**A.** I think the data shows that it has. That's my personal experience.

**Q.** And in your opinion, do physicians affect the standard of care?

**A.** Well, physicians determine the standard of care, if you will, because we, we hold each other accountable for what we're doing and we learn from each other. Sometimes we learn things that later prove to be untrue based on new research and development.

So that's why the standard of care changes. I may have an opinion in 1997 that in 2015 you see that was incorrect looking backward. So it changes based on new information. That's why research is so important and that's why, you know, a big part of my practice is research and development.

**Q.** Did the DEA affect the standard of care?

**A.** I think it did. I think the local DEA people I know are wonderful people and very good, but nationally the policies that Ms. Tandy and others --

MR. FITZSIMMONS: Judge, I'm going to object to him testifying about policies of the DEA.

THE COURT: Sustained.

MR. FITZSIMMONS: I don't think he's qualified.

BY MS. MAINIGI:

**Q.** Did the VA affect the standard of care?

**A.** Yes. The VA policies on fifth vital sign affected standard of care.

**Q.** And did the Joint Commission affect the standard of care?

**A.** Joint Commission definitely affected the standard of care.

**Q.** And I think you've already answered this, but did West Virginia's legislature affect the standard of care?

**A.** Legislation definitely affected the standard of care.

**Q.** And did West Virginia's Board of Medicine affect the standard of care?

**A.** Board of Medicine certainly helps determine the standard of care.

**Q.** In your opinion, based on your experience and your understanding, did wholesale distributors have any affect on

the rate at which doctors in West Virginia prescribed opioids?

MR. FITZSIMMONS: Judge, this is the third time, I think, that I've objected. He's been designated not to testify -- he doesn't know anything about distributors.

THE COURT: Well, you'll have to lay a basis for it, Ms. Mainigi. I think the question is objectionable as it stands.

MS. MAINIGI: Okay, Your Honor. I'll just withdraw the question for now.

BY MS. MAINIGI:

**Q.** Dr. Deer, in terms of your own practice, explain to us how your practice is a mirror on what's happened in West Virginia.

**A.** Well, I believe that, you know, when we -- when you take patients off the street because they requested seeing you or you get a family doctor or you are a specialist, you will get patients based on who's heard about your practice or how you market or advertise your practice.

As a referral only practice, we actually receive patients that, again, throughout the State of West Virginia and they're sent to see us already undergoing certain treatments.

As we talked about earlier, you know, 10 years ago everyone was on high-dose opioids. Now we're seeing other

things being tried. So I think it goes to show you that West Virginia, greatest state in America in my opinion -- I know you're not from here -- we've made a good effort to change things as a whole and we've evolved. Hopefully we'll continue to evolve for the better and we'll continue to make progress.

**Q.** Thank you, Dr. Deer.

MS. MAINIGI: I have no further questions, Your Honor. I'd like to go ahead and mark the timeline as Cardinal Demonstrative Number 2 and provide a copy to the Court.

THE COURT: You may do so. And it's five till 12:00. Let's adjourn until 2:00 rather than start your cross-examination, Mr. Fitzsimmons. Is that okay with you?

MR. FITZSIMMONS: That's good with me, Judge.

THE COURT: Okay.

We have to ask you to come back at 2:00, Dr. Deer.

THE WITNESS: Yes, sir. Thank you, sir.

THE COURT: We'll see everybody at 2:00.

MS. MAINIGI: Thank you, Your Honor.

(Recess taken at 11:55 a.m.)

THE COURT: If you'll resume the witness stand, Dr. Deer.

THE WITNESS: Thank you, sir.

THE COURT: All right, sir. You may proceed.